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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,134	07/11/2003	Gerold Schuler	106985-2 KGB	4429
27384 7590 03/16/2009 NORRIS, MCLAUGHLIN & MARCUS, PA 875 THIRD AVENUE 18TH FLOOR NEW YORK, NY 10022				
EXAMINER				
JUEDES, AMYE				
ART UNIT		PAPER NUMBER		
1644				
MAIL DATE		DELIVERY MODE		
03/16/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/618,134

**Applicant(s)**

SCHULER ET AL.

**Examiner**

AMY E. JUEDES

**Art Unit**

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9, 11, 29, 30 and 35-38 is/are pending in the application.
- 4a) Of the above claim(s) 36 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9, 11, 29, 30, 35 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 1/2/09, 1/5/09.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed 1/2/09 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/2/09 has been entered.

Claims 9 and 11 have been amended.

Claims 9, 11, 29-30, and 35-38 are pending.

Claims 36 and 38 stand withdrawn from further consideration pursuant to 37 CFR 1.14209 as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 9, 11, 29-30, 35, and 37 are under examination.

2. Applicant's information disclosure, filed 1/5/09, is acknowledged. However, the Read et al. citation has been lined through since it a duplicate of the citation already considered on the IDS filed 1/2/09.

3. The rejection of the claims under 35 U.S.C. 103 is withdrawn in view of Applicant's submission of a declaration under 37 CFR 1.131 demonstrating completion of the instant invention prior to the publication date of Jonuleit et al.

4. The rejection of the claims under 35 U.S.C. 112 first paragraph for new matter as set forth in paragraph 4 of the previous office action is withdrawn in view of Applicant's amendment to the claims.

5. Upon reconsideration, the rejection of the claims under 35 U.S.C. 112 first paragraph for new matter for the recitation of "activated" CD4+CD25+ T cell is withdrawn. The specification on pages 9 discloses anergizing CD4+CD25- T cells with previously activated CD4+CD25+ T cells.

6. The following are new grounds of rejection.

Art Unit: 1644

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 9, 11, 29-30, 35, and 37 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by US Patent Application Publication 2002/0090357, as evidenced by Fujimaki et al., 2008.

The '357 publication teaches a method of making IL-10 producing Tr1 regulatory T cells comprising culturing naive CD45RA+CD4+ human T cells with anti-CD3 and anti-CD28 antibodies in the presence of immunosuppressive agents ex vivo (see page 2, 4, and 8 in particular). Furthermore, as evidenced by Fujimaki et al., naive CD45RA+ human CD4 + T cells comprise both CD25+ cells and CD25- cells. Thus, culturing total naive CD4+ T cells, as taught by the '357 publication, inherently involves "co-culturing" both CD4+CD25+ T cells and CD4+CD25- T cells, as recited in the instant claims. Additionally, said T cells are "activated" by the culture with anti-CD3 and anti-CD28. Additionally, the '357 publication teaches stimulating with plate bound anti-CD3 and soluble anti-CD28 (see pages 8-9, in particular). Furthermore, the '357 publication teaches that regulatory T cells have the capacity to inhibit T cell proliferation in vitro (see page 1 in particular).

Thus, the reference clearly anticipates the invention.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, whose telephone number is 571-272-4471. The examiner can normally be reached on 7am to 3:30pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy E. Juedes  
Patent Examiner  
Technology Center 1600

/G.R. Ewoldt/  
Primary Examiner, Art Unit 1644